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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/722,070

11/24/2000

Brian S. Kelleher

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09/07/2006

JONATHAN SPANGLER

NU VASIVE, INC.

4545 TOWNE CENTRE COURT

SAN DIEGO, CA 92121

EXAMINER

DOERRLER, WILLIAM CHARLES

ART UNIT

PAPER NUMBER

3744

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/722,070

Applicant(s)

KELLEHER ET AL.

Examiner

William C. Doerrler

Art Unit

3744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 22-26 and 30-39 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 15, 16, 22-26 and 30-39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15,16,22-26,30,31 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al '331 in view of Feler et al.

Raymond et al '331 discloses applicants' basic inventive concept, a method for determining the location of a nerve by electrically signaling the nerve and detecting (using EMG in lines 38 and 40 of column 11) the response and determining when the signal is below a threshold signifying close proximity to the nerve (see abstract) and using a visual or audible alarm to signal the proximity to the nerve, substantially as claimed with the exception of using the process on a spinal nerve. While this is seen as

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a matter of design choice since all the nerves in a body function on the same principle, Feler et al nevertheless shows electrically determining the location of spinal nerves to be known in the art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Feler et al to modify the detection system of Raymond et al '331 by enabling the use for spinal nerves to enable safe operations in the vicinity of the spinal cord. Tone module 20 of Raymond et al is seen as a means to indicate the intensity of the signal.

Claims 15,16,22-26 and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al '153 in view of Feler et al.

Raymond et al '153 discloses applicants' basic inventive concept, a method for determining the location of a nerve by electrically signaling the nerve and detecting the response using EMG (column 6 line 12 of '153) and determining when the signal is below a threshold signifying close proximity to the nerve (see column 3 lines 21-55) and using a visual or audible alarm to signal the proximity to the nerve, thus signaling the intensity of the signal,(column 7 lines 3-23), substantially as claimed with the exception of using the process on a spinal nerve. While this is seen as a matter of design choice since all the nerves in a body function on the same principle, Feler et al nevertheless shows electrically determining the location of spinal nerves to be known in the art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Feler et al to modify the detection system of Raymond et al '153 by enabling the use for spinal nerves to enable safe operations in the vicinity of the spinal cord. In regard to claim 32, iteration to determine the proper position of the

nerve is seen as well within the scope of the ordinary practitioner as a confirmation of the placement of the nerve to reduce the chances of an accidental an irreparable severing of the nerve. The first paragraph of column 7 discusses the signaling of the intensity which detects the nerve.

Response to Arguments

Applicant's arguments filed 8-11-2006 have been fully considered but they are not persuasive. In the opinion of the examiner it is still obvious to approach a nerve from a perpendicular direction from a lateral surface of the nerve. Applicant has stated that figures 1-4 clearly show that the probes approach the nerve from the lateral direction of the spine. The examiner does not agree with this assessment. Figures 1 and 4 are top views which show the probes on the sides of the nerve, but it is unclear if the probes are coming directly from the sides or at a steep angle. Without a side view, it is impossible to determine. In the opinion of the examiner, since all nerves in the human body function generally the same, the teaching of the references is applicable to any nerve. Applicants have stated on page 8 and 9 of the response reasons why the approach from the lateral direction is advantageous. These advantages are seen as well known to the ordinary practitioner in the art. The typical surgeon would recognize these benefits. It is further noted that nowhere in the written description as originally filed is there any discussion as to the benefits of a lateral approach. This is taken as evidence that such an approach would have been obvious to an ordinary practitioner in the art. If applicant desires to make part of the inventive concept of his protected claims that a lateral approach is more beneficial than any other approach, applicant will need to file a

continuation in part application. The examiner did not object to the language specifying a lateral approach as new matter, as the examiner felt that such an approach, and the benefits and consequences of such an approach, are well within the scope of the ordinary practitioner. If applicant feels otherwise, a CIP filing would be proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William C. Doerrler whose telephone number is (571) 272-4807. The examiner can normally be reached on Monday-Friday 6:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cheryl Tyler can be reached on (571) 272-4834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William C Doerrler
Primary Examiner
Art Unit 3744

WCD